DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

91702d

September 4, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 – 73

Howard D. Larson
President/Owner
Radiation Products Design, Inc.
5218 Barthel Industrial Drive
Albertville, Minnesota 55301

Dear Mr. Larson:

During an inspection of your establishment located in Albertville, MN, on July 23 and 24, 2001, our investigator determined that your establishment manufactures radiation accessory products which are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), as follows:

1. Failure to conduct management reviews as required by 21 CFR 820.20(c).

2. Failure to establish quality audit procedures and failure to conduct such audits as required by 21 CFR 820.22.

3. Failure to establish complete procedures for corrective and preventive action as required by 21 CFR 820.100. For example, your corrective and preventive action procedures are limited only to processing of customer complaints.

4. Failure to analyze all quality data sources to identify existing and potential causes of non-conforming product or other quality problems. This is required by 21 CFR 820.100. For example, non-conforming returned products and receiving inspection data are not being reviewed.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act as follows:

5. Failure to develop written procedures for Medical Device Reporting (MDR) as required by 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TGP/ccl